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GAU 1625

DOCKET NO.: CELL-0072 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:
Porter et al.

Serial No.: 09/326,020 **Group Art Unit: 1625**

Filing Date: June 4, 1999 **Examiner: B. Robinson**

For: PHENYLALANINE DERIVATIVES

DATE OF DEPOSIT: March 29, 2001

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE ASSISTANT COMMISSIONER FOR PATENTS, WASHINGTON, DC 20231.

Gregory L. Hillyer
REGISTRATION NO.: 44,154

04/03/2001 SHINASS1 00000060 09326020
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Assistant Commissioner for Patents
Washington DC 20231

Sir:

AMENDMENT TRANSMITTAL LETTER

Transmitted herewith for filing in the above-identified patent application is:

☐ A Preliminary Amendment.

☒ An Amendment Responsive to the Office Action Dated January 29, 2001.

☐ An Amendment Supplemental to the Paper filed _____.

☐ Other: _____.

☐ Small entity status of this application under 37 C.F.R. 1.9 and 1.27 was established in a previous submission.

☐ A Statement Claiming Small Entity Status under 37 C.F.R. 1.9 and 1.27 is enclosed.

☐ This application is no longer entitled to small entity status. It is requested that this be noted in the files of the Patent and Trademark Office.

☐ Substitute Pages _____ of the Specification are enclosed.

☐ An Abstract is enclosed.

☐ _____ Sheets of Proposed Corrected Drawings are enclosed.

☐ A Certified Copy of each of the following applications: _____ _____ is enclosed.

☐ An Associate Power of Attorney is enclosed.

☐ Information Disclosure Statement.

- ☐ Attached Form 1449.
- ☐ A copy of each reference as listed on the attached Form PTO-1449 is enclosed herewith.

☐ Appended Material as follows: _____ .

☐ Other Material as follows: _____ .

FEE CALCULATION

☐ No Additional Fee is Due.

				SMALL ENTITY		NOT SMALL ENTITY	
	REMAINING AFTER AMENDMENT	HIGHEST PAID FOR	EXTRA	RATE	FEE	RATE	FEE
TOTAL CLAIMS	19	20 (20 MINIMUM)	0	$9 EACH	$	$18 EACH	$
INDEP. CLAIMS	3	3 (3 MINIMUM)	0	$39 EACH	$	$78 EACH	$
FIRST PRESENTATION OF MULTIPLE DEPENDENT				$130	$	$260	$
☒ ONE MONTH EXTENSION OF TIME				$55	$	$110	$110.00
☐ TWO MONTH EXTENSION OF TIME				$190	$	$380	$
☐ THREE MONTH EXTENSION OF TIME				$435	$	$870	$
☐ FOUR MONTH EXTENSION OF TIME				$680	$	$1360	$
☐ FIVE MONTH EXTENSION OF TIME				$925	$	$1850	$
☐ LESS ANY EXTENSION FEE ALREADY PAID				minus	($)	minus	($)
☐ TERMINAL DISCLAIMER				$55	$	$110	$
☐ OTHER FEE OR SURCHARGE AS FOLLOWS:							
TOTAL FEE DUE							$110.00

☒ A Check is Enclosed in the Foregoing Amount Due.

☒ Petition is hereby made under 37 C.F.R. 1.136(a) to extend the time for response to the Office Action of **January 29, 2001** to and through **March 29, 2001** comprising an extension of the shortened statutory period of **1** month(s).

☒ The Commissioner is hereby requested to grant an extension of time for the appropriate length of time, should one be necessary, in connection with this filing or any future filing submitted to the U.S. Patent and Trademark Office in the above-

identified application during the pendency of this application. The Commissioner is further authorized to charge any fees related to any such extension of time to deposit account 23-3050. This sheet is provided in duplicate.

☒ The Commissioner is authorized to charge payment of the following fees and to refund any overpayment associated with this communication or during the pendency of this application to deposit account 23-3050. This sheet is provided in duplicate.

☐ The Foregoing Amount Due for Filing this Paper.

☒ Any additional filing fees required, including fees for the presentation of extra claims under 37 C.F.R. 1.16.

☒ Any additional patent application processing fees under 37 C.F.R. 1.17 or 1.20(d).

SHOULD ANY DEFICIENCIES APPEAR with respect to this application, including deficiencies in payment of fees, missing parts of the application or otherwise, the United States Patent and Trademark Office is respectfully requested to promptly notify the undersigned.

Date: March 29, 2001

Gregory L. Hillyer
Registration No. 44,154

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#23
4/5/01

DOCKET NO.: CELL-0072 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:

John Robert Porter, John Clifford Head,
Graham John Warrellow, and Sarah Catherine Archibald

Serial No.: **09/326,020** Group Art Unit: **1625**

Filed: **June 4, 1999** Examiner: **B. Robinson**

For: **PHENYLALANINE DERIVATIVES**

I, **Gregory L. Hillyer, Registration No. 44,154** certify that this correspondence is being deposited with the U.S. Postal Service as First Class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

On March 29, 2000

Gregory L. Hillyer, Reg. No. 44,154

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

REPLY UNDER 37 C.F.R. § 1.146 TO
OFFICE ACTION DATED JANUARY 29, 2001

This is in response to the Requirement For Restriction mailed on January 29, 2001.

A restriction has been required to one of three groups of inventions, classified as Groups I, II, and III. Group I (claims 1-19) is drawn to a compound of formula (Ia) wherein R^1 is an optionally substituted phenyl, a method of treating diseases comprising administering a compound of formula (Ia) wherein R^1 is an optionally substituted phenyl, a method of inhibiting

an α4β7 integrin binding to ligands comprising administering a compound of formula (Ia) wherein R^1 is an optionally substituted phenyl, and pharmaceutical compositions comprising a compound of formula (Ia) wherein R^1 is an optionally substituted phenyl. Group II (claims 1-19) is drawn to a compound of formula (Ia) wherein R^1 is an optionally substituted pyridyl, a method of treating diseases comprising administering a compound of formula (Ia) wherein R^1 is an optionally substituted pyridyl, a method of inhibiting an α4β7 integrin binding to ligands comprising administering a compound of formula (Ia) wherein R^1 is an optionally substituted pyridyl, and pharmaceutical compositions comprising a compound of formula (Ia) wherein R^1 is an optionally substituted pyridyl. Group III (claims 1-19) is drawn to a compound of formula (Ia) wherein R^1 is an optionally substituted pyrimidinyl, a method of treating diseased comprising administering a compound of formula (Ia) wherein R^1 is an optionally substituted pyrimidinyl, a method of inhibiting an α4β7 integrin binding to ligands comprising administering a compound of formula (Ia) wherein R^1 is an optionally substituted pyrimidinyl, and pharmaceutical compositions comprising a compound of formula (Ia) wherein R^1 is an optionally substituted pyrimidinyl.

It is asserted in the Office Action that Groups I, II, and III are unrelated in that they have different modes of operation, different functions, or different effects. Specifically, the Office Action contends that the "different inventions" can be used as inhibitors of beta amyloid protein production or as protease inhibitors. The mere fact, however, that certain phenylalanine derivatives may inhibit beta amyloid protein production or protease, does not mean that these

derivatives have different modes of operation, functions, or effects *in the disclosed invention.* Thus, it is submitted respectfully that the restriction requirement is deficient in that a showing has not been made that the involved claims are directed to independent inventions.[1] Inventions are only deemed "independent" if there is no disclosed relationship and/or if the inventions are unconnected in design, operation or effect. *See* M.P.E.P. §802.01. Applicants, however, *have* disclosed a common relationship involving, *inter alia*, inhibition of $\alpha 4\beta 7$ integrin by compounds having a common phenylalanine core. This common relationship establishes that the subject matter is not misjoined as the Office Action suggests.

The purpose of § 121 is to avoid a situation which requires that separate and diverse searches be conducted on claims directed to independent (unrelated) subject matter. That is not the situation here because the relationship among the compounds of formula (Ia) is such that a reasonable search for phenylalanine derivatives generally would necessarily lead to disclosures, to the extent any exist, of compounds wherein R^1 is either an optionally substituted phenyl, pyridyl, or pyrimidinyl. Accordingly, Applicants submit respectfully that it is incumbent upon the Examiner to conduct such a search.

Applicants hereby elect for prosecution Group II (claims 1-19), which is drawn to a compound of formula (Ia) wherein R^1 is an optionally substituted pyridyl, a method of treating diseases comprising administering a compound of formula (Ia) wherein R^1 is an optionally

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[1] 35 U.S.C. §121 states that an application can be restricted if two or more inventions are, *inter alia*, independent.

substituted pyridyl, a method of inhibiting an α4β7 integrin binding to ligands comprising administering a compound of formula (Ia) wherein R^1 is an optionally substituted pyridyl, and pharmaceutical compositions comprising a compound of formula (Ia) wherein R^1 is an optionally substituted pyridyl, with traverse. Applicants hereby affirm the right to file one or more divisional applications with respect to any of the non-elected subject matter.

Conclusion

Applicant believes that the foregoing constitutes a complete and full response to the Office Action of record. Accordingly, an early and favorable action on the merits is requested respectfully.

Respectfully submitted,

Gregory L. Hillyer
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Date: March 29, 2001
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